CAPIOX® Cardiotomy Reservoir

Submitter Information:
This premarket notification is submitted by:

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Terumo Cardiovascular Systems
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Date of Preparation: February 13, 2003

Device Names:

Proprietary Name:	CAPIOX® Cardiotomy Reservoir
Common Name:	Blood Reservoir
Classification:	CPB Reservoirs are classified as Class II devices.

Predicate Device:
The CAPIOX® Cardiotomy Reservoir is substantially equivalent in intended use, materials, design, technology and principles of operation, and performance to the CAPIOX® RX Hardshell Reservoir (K013526).

Intended Use:
The CAPIOX® Cardiotomy Reservoir is designed to facilitate the removal of particulate matter and micro air bubbles from blood that is aspirated from the thoracic cavity and/or the left ventricle, and store it during extra corporeal circulation. The device may be used for procedures lasting up to 6 hours.

Principles of Operation/Technology:
The CAPIOX® Cardiotomy Reservoir is used as a blood storage device during and after cardiopulmonary bypass procedures. The patient's blood enters the reservoir from the thoracic cavity and/or the left ventricle. Typically, the blood is pulled into the reservoir via suction.

The blood that is drawn from the patient enters the device via the blood inlet ports and suction ports that are positioned above the cardiotomy filter that is contained within the reservoir. The blood passes through a defoamer (to remove air from the blood) and through a filter (for mechanical entrapment/removal) of particulate matter from the blood.

Blood exits the device via gravity through the blood outlet port and is subsequently pumped through the remainder of the cardiopulmonary bypass circuit.

Design and Materials:
The *design* of the CAPIOX® Cardiotomy Reservoir is comprised of a hardshell casing that serves as a blood containment system within the bypass circuit. The upper portion of the reservoir consists of a hardshell lid assembly that contains the necessary inlet ports and vent ports. The total capacity of the reservoir is 4000 mL.

The cardiotomy section of the CAPIOX® Cardiotomy Reservoir contains a defoamer and a filter to facilitate air removal and the removal of particulates from suctioned blood entering the reservoir.

The generic *materials* used in the CAPIOX® Cardiotomy Reservoir are polycarbonate, polypropylene, PET, polyvinyl chloride, polyurethane, nylon, stainless steel, ceramic and Terumo's X-Coating polymer solution.

Performance Evaluations:
The performance of the CAPIOX® Cardiotomy Reservoir is substantially equivalent to the performance of the cardiotomy section of the predicate device. The following tests were conducted to demonstrate equivalence in performance:

- Filter Defoaming – Cardiotomy Section
- Pressure Drop – Cardiotomy Section
- Filtration Efficiency – Cardiotomy Section
- Effects Upon Cellular Blood Components
- Pressure Integrity Testing
- Tubing Connection Strength
- Filter Breakthrough Time

Substantial Equivalence Comparison:
The CAPIOX® Cardiotomy Reservoir is substantially equivalent to cardiotomy section of the predicate CAPIOX® RX Hardshell Reservoir device as follows:

Intended Use: The CAPIOX® Cardiotomy Reservoir and the predicate RX Hardshell Reservoir share the same intended uses. Each is used to facilitate the removal of particulate matter and micro air bubbles from blood that is aspirated from the thoracic cavity and/or the left ventricle, and store it during extra corporeal circulation. Each device may be used for procedures lasting up to 6 hours.

Principles of Operation/Technology: The CAPIOX® Cardiotomy Reservoir and the predicate RX Hardshell Reservoir utilize the same technology in their respective operations. With each device, the patient's blood enters the reservoir from the thoracic cavity and/or the left ventricle. Typically, the blood is pulled into the reservoir via suction.

The blood that is drawn from the patient enters the devices via the blood inlet ports and suction ports that are positioned above the cardiotomy filter that is contained within the reservoirs. The blood passes through a defoamer (to remove air from the blood) and through a filter (for mechanical entrapment/removal) of particulate matter from the blood.

Blood exits the devices via gravity through the blood outlet port and is subsequently pumped through the remainder of the cardiopulmonary bypass circuit.

Design and Materials: The design of the CAPIOX® Cardiotomy Reservoir is identical to the predicate RX Hardshell Reservoir except that it does not contain a venous filter. As such, the materials are also identical for the two devices, excepting that a venous filter is not present in the CAPIOX® Cardiotomy Reservoir. There are no new and/or additional materials utilized in the CAPIOX® Cardiotomy Reservoir that are not also utilized in the predicate RX Hardshell Reservoir.

Performance: The cardiotomy section of the CAPIOX® Cardiotomy Reservoir is exactly the same as the cardiotomy section of the predicate RX Hardshell Reservoir. As such, there are no performance differences between the cardiotomy sections of the two devices. The removal of the venous filter does not alter the performance of the cardiotomy filter, as the two filters operate and perform independently of each other.

Substantial Equivalence Summary:
In summary, the CAPIOX® Cardiotomy Reservoir and the predicate RX Hardshell Reservoir are substantially equivalent in intended use, principles of operation/technology, design and materials, and performance. Any noted differences between the devices do not raise new issues of safety and effectiveness.

Additional Safety Information:

- Sterilization conditions have been validated in accordance with AAMI guidelines to provide a Sterility Assurance Level (SAL) of 10^{-6}.

- Ethylene Oxide residues will not exceed the maximum residue limits proposed for Part 821 of Title 21 in the Federal Register of June 23, 1978 (or as finalized or amended).

- Biocompatibility studies were conducted on the predicate device as recommended in the FDA General Program Memorandum #G95-1 (5/1/95): Use of International Standard ISO 10993, "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing." [External Communicating Devices, Circulating Blood, Limited Exposure (≤ 24 hours) Contact Duration]. The blood contacting materials were found to be biocompatible. It is not necessary to conduct these studies on the new CAPIOX® Cardiotomy Reservoir since the materials and design are exactly the same

as those of the predicate device (except that a venous filter is not included in the subject device).

Conclusion:

In summary, the CAPIOX® Cardiotomy Reservoir is substantially equivalent in intended use, principles of operation/technology, design and materials, and performance to the cardiotomy section of the predicate RX Hardshell Reservoir (K013526).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 1 4 2003

Terumo Cardiovascular Systems Corporation
c/o Mr. Garry A. Courtney
125 Blue Ball Road
Elkton, MD 21921

Re: K030505
CAPIOX® Cardiotomy Reservoir
Regulation Number: 21 CFR 870.4400
Regulation Name: Cardiopulmonary Bypass Blood Reservoir
Regulatory Class: Class II (two)
Product Code: DPW
Dated: February 13, 2003
Received: February 19, 2003

Dear Mr. Courtney:

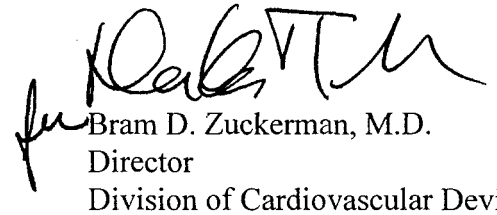
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K030505

Device Name: **CAPIOX® Cardiotomy Reservoir**

Indications For Use:

The CAPIOX® Cardiotomy Reservoir is designed to facilitate the removal of particulate matter and micro air bubbles from blood that is aspirated from the thoracic cavity and/or the left ventricle, and store it during extra corporeal circulation. The device may be used for procedures lasting up to 6 hours.

Feb 13, 2003

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Terumo Cardiovascular Systems

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K030505

Prescription Use X OR Over-The-Counter Use _____

(Per 21 CFR 801.109)